MAR 2 4 2006

K 060215

510(k) Summary

Submitter:	Eurotrol B.V. Keplerlaan 20 6716 BS Ede, The Netherlands +31 318 695777 (Telephone) +31 318 695770 (FAX)
Contact:	Allan White (Official Correspondent) HemoCue, Inc. 40 Empire Drive Lake Forest, CA 92630-2244 (800) 881-1611 x110 (Telephone) (949) 859-3066 (FAX) allan@hemocue.com
Date of Preparation:	January 18, 2006
Proprietary Name:	AlbuTrol Low and AlbuTrol High
Classification Name:	Quality control material (assayed and unassayed) (21 CFR 862.1660, Product Code JJX)
Common Name:	AlbuTrol
Equivalent to:	MAS® UA Control, 510(k) document control number K023928

Description

AlbuTrol is an assayed urine albumin control material. AlbuTrol control material is filled of in dropper bottles. Each dropper bottle contains 1.0 mL human urine with a specific amount of human albumin. AlbuTrol provides two physiologically relevant levels covering the clinically interesting ranges of urine albumin: ~25 mg/L albumin and ~75 mg/L albumin.
The assigned values of each batch are printed on both the carton box and the dropper bottles.
AlbuTrol is packed in carton boxes. Each carton box contains 2 dropper bottles of the same level on a carton tray. An insert with Intended Use is packed in each box of AlbuTrol.

Intended Use

AlbuTrol is an assayed albumin control intended for professional use in the verfication of the precision and accuracy of the HemoCue Urine Albumin system and the HemoCue Albumin 201 system. On these systems, AlbuTrol performs in the same way as human urine does. AlbuTrol is for in vitro use only. **AlbuTrol is for professional use only.**

Technological Characteristics

AlbuTrol is filled in 3 mL dropper bottles made of Low Density Polyethylene. Each dropper bottle is capped with a dropper tip and a colored cap, both made of polypropylene.

Values of AlbuTrol are assigned on factory calibrated HemoCue Albumin 201 systems. The stability of AlbuTrol is 9 months from value assignment.
To obtain a drop of control material the dropper bottle needs to be pressed slightly. After dispense of a drop of the control material onto a hydrophobic surface, for example a plastic film, the sample is drawn into the microcuvette by capillary force. After that the microcuvettes need to be inserted into the system for measuring immediately.

Assessment of Performance

Studies were conducted in-house to demonstrate the performance on the HemoCue Urine Albumin system and the HemoCue Albumin 201 analyzing system.

Conclusion

The AlbuTrol control materials are convenient control materials for professional use in the verfication of the precision and accuracy of the HemoCue Urine Albumin system and the HemoCue Albumin 201 system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 4 2006

EuroTrol B.V.
c/o Mr. Allan White
Quality Systems Manager
HemoCue, Inc.
40 Empire Drive
Lake Forest, CA 92630

Re: k060215
Trade/Device Name: AlbuTrol
Regulation Number: 21 CFR§862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJX
Dated: March 15, 2006
Received: March 16, 2006

Dear Mr. White:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060215

Device Name: AlbuTrol

Indications For Use:

AlbuTrol is an assayed albumin control intended for professional use in the verification of the precision and accuracy of the HemoCue® Urine Albumin and HemoCue® Albumin 201 systems.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K060215